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10/786,562

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Burton H. Sage JR.

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EXAMINER

SCHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/786,562 | <b>Applicant(s)</b><br>SAGE, BURTON H. |  |
|                              | <b>Examiner</b><br>LAURA C. SCHELL   | <b>Art Unit</b><br>3767                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6932796.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the application and the patent claim similar subject matter.

Claims 1-60 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 7268859.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the application and the patent claim similar subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-25, 31-48, 51-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yin et al. (US Patent No. 6,386,050) in view of Fritz (US 2007/0188737). Yin discloses a system and method for monitoring and measuring fluid flow through a passageway (Figs. 1-9) comprising: a heater (Fig. 4, heater is 42 for example) that heats a portion of the fluid in the passageway (Fig. 4 for example can be interpreted as heating a portion of the fluid in the passageway as the laser only heats the portion of the fluid in the passageway that passes by the laser. The laser does not heat the entire length of the fluid passageway and therefore does not heat more than a portion of the fluid in the fluid passageway); a light source (24) that generates a beam of light that illuminates the fluid in the passageway; and a light detector (56) positioned to

receive a portion of the beam, wherein the detector measures a change in the intensity of the beam when the heated portion of the fluid passes through the beam (abstract).

Yin further discloses that the light detector is positioned along the axis such that the light detector measures a decreased intensity with the passage of the heated portion of the fluid, as well as the light detector being displaced from the axis such that the light detector measures an increased intensity with the passage of the heated portion of the fluid (Figs. 1, 4 and 8). Yin also discloses using liquid as the fluid and using an infrared laser (abstract). Yin further discloses that the distance is fixed for the purpose of calculations (col. 7, lines 61-63) and that the time period is measured for calculation purposes (col. 3, lines 33-36) and the velocity is calculated (col. 1, lines 35-38). Also see col. 2, line 50 through col. 5, line 21; col. 7, lines 9-63; col. 7, line 64 through col. 8, line 37; col. 6, lines 15-16. In col. 6, lines 51-57. Yin, however, does not disclose that the detector measures a change in intensity of the beam by diffraction of the beam.

Fritz, however, discloses a similar device which measures the velocity of a particle in fluid flow by using a light source on one side of the fluid passageway and a light detector on the opposite side of the fluid passageway. The velocity of the particle traveling through the device is determined by detecting the intensity of the diffracted light as the particle passes through the path of the light source and light detector (paragraph [0011], [0041], [0048], [0061] and [0077]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Yin by using light detectors to detect the intensity of the light beam caused by diffraction of the beam as the portion of fluid passes through, as Fritz teaches that this type of

diffraction detection is known in the art and used to detect/measure the velocity of particles traveling through a fluid passageway.

Claims 26-30, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frank et al. (US Patent No. 5,211,626) in view of Yin et al. (US Patent No. 6,386,050) and further in view of Fritz (US 2007/0188737). Frank discloses the device substantially as claimed including a device for delivering a liquid medicament to a subject (Figs. 1-5) comprising: a system for monitoring fluid flow (14) through a passageway (through passageway 50) and a valve for starting and stopping liquid flow in the flow tube in a periodic manner based on information from the system (20). Frank further discloses that the fluid is heated at a certain position and then infrared sensors are used to detect the heat pulse and calculate the flow rate (abstract and fig. 1). Frank, however, does not disclose the details of monitoring system such as a light source, light detector and the positioning of the heater, light source and light detector relative to each other. Yin, however, discloses a system and method for monitoring and measuring fluid flow through a passageway (Figs. 1-9) comprising: a heater (Fig. 4, heater is 42 for example) that heats a portion of the fluid in the passageway (Fig. 4 for example can be interpreted as heating a portion of the fluid in the passageway as the laser only heats the portion of the fluid in the passageway that passes by the laser. The laser does not heat the entire length of the fluid passageway and therefore does not heat more than a portion of the fluid in the fluid passageway); a

light source (24) that generates a beam of light that illuminates the fluid in the passageway; and a light detector (56) positioned to receive a portion of the beam, wherein the detector measures a change in the intensity of the beam when the heated portion of the fluid passes through the beam (abstract). Yin further discloses that the light detector is positioned along the axis such that the light detector measures a decreased intensity with the passage of the heated portion of the fluid, as well as the light detector being displaced from the axis such that the light detector measures an increased intensity with the passage of the heated portion of the fluid (Figs. 1, 4 and 8). Yin also discloses using liquid as the fluid and using an infrared laser (abstract). Yin further discloses that the distance is fixed for the purpose of calculations (col. 7, lines 61-63) and that the time period is measured for calculation purposes (col. 3, lines 33-36) and the velocity is calculated (col. 1, lines 35-38). Also see col. 2, line 50 through col. 5, line 21; col. 7, lines 9-63; col. 7, line 64 through col. 8, line 37; col. 6, lines 15-16. In col. 6, lines 51-57. Yin, however, does not disclose that the detector measures a change in intensity of the beam by diffraction of the beam. Fritz, however, discloses a similar device which measures the velocity of a particle in fluid flow by using a light source on one side of the fluid passageway and a light detector on the opposite side of the fluid passageway. The velocity of the particle traveling through the device is determined by detecting the intensity of the diffracted light as the particle passes through the path of the light source and light detector (paragraph [0011], [0041], [0048], [0061] and [0077]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Yin by using light detectors to detect the

intensity of the light beam caused by diffraction of the beam as the portion of fluid passes through, as Fritz teaches that this type of diffraction detection is known in the art and used to detect/measure the velocity of particles traveling through a fluid passageway.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Frank with the detailed monitoring system as taught by Yin in view of Fritz, in order to provide a more accurate system for measuring the fluid flow, as a medical device which delivers a medicament to a patient must be as accurate as possible in order to prevent over or under-dosing which are potentially life threatening conditions for a patient.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-60 have been considered but are moot in view of the new ground(s) of rejection.

With respect to Applicant's arguments that Yin does not teach heating only a portion of the fluid in the passageway, it is the examiner's position that Yin does teach only heating a portion of the fluid, as the light source does not span the entire length of the fluid passageway (which would then heat the entirety of the fluid in the passageway). Instead it is at only one position along the passageway and therefore heats only a portion of the fluid passageway.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767